

Sources Sought Notice

Sources Sought Notice No.: SS-ETSB-2007-48

Title: “Central Institutional Review Board (CIRB) Initiative”

This Sources Sought Notice (SS) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute (NCI).

The purpose of this SS is to identify qualified small business concerns [including Small Disadvantaged Businesses (SDB), Woman-owned Small Businesses (WOSB), Historically Underutilized Business Zone (HUBZone) Small Businesses, Veteran-Owned Small Businesses (VOSB) and Service-Disabled Veteran-owned Small Businesses (SDVOSB)] that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses nor otherwise pay for the preparation of any information submitted. As a result of this Sources Sought notice, the NCI may issue a Request for Proposal (RFP). THERE IS NO SOLICITATION AVAILABLE AT THIS TIME. However, should such a requirement materialize, no basis for claims against NCI shall arise as a result of a response to this Sources Sought notice or the NCI’s use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute’s (NCI) Division of Cancer Treatment and Diagnosis (DCTD) is seeking capability statements from all eligible small business concerns [particularly Small Disadvantaged Businesses (SDB), Woman-owned Small Businesses (WOSB), Historically Underutilized Business Zone (HUBZone) Small Businesses, Veteran-Owned Small Businesses (VOSB) and Service-Disabled Veteran-owned Small Businesses (SDVOSB)] under the North American Industry Classification System (NAICS) code 541690, with a size standard of \$6,500,000 per annum. Based on the responses received from this SOURCES SOUGHT announcement, the proposed acquisition may be solicited as a Total Small Business Set-Aside. All eligible small business concerns responding to this Sources Sought Announcement must have the capabilities to provide on-going, comprehensive support for two functioning IRBs (one for adult trials and the other for pediatric trials), as well as facilitate new site enrollments and provide support for existing local IRBs participating in the Initiative. In addition, the Contractor shall facilitate the NCI’s efforts to promote the expansion of the Initiative to approximately 600 additional sites currently conducting NCI Cooperative Group trials.

Major tasks required of the Contractor include the following:

- Manage and provide administrative and regulatory support for two Central IRBs (one for adult trials and one for pediatric trials);
- Manage and support current and newly enrolled local sites;

- Support the recruitment of new sites and conduct their integration into the Initiative;
- Provide informatics systems to support all operations;
- Support communications with NCI and stakeholders regarding all aspects of the Initiative; and
- Implement and manage an Initiative-wide Quality Improvement Plan.

In addition, the following Optional Tasks may be required of the Contractor:

- Provide support for obtaining Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation in contract year 1 or 2, as determined by NCI;
- Establish and maintain informatics to support Board meeting responsibilities;
- Manage and support an additional adult CIRB, if required, as a result of expanding the pool of trials reviewed by the CIRB;
- Enhance and update CIRB Initiative Informatics system to ensure compliance with the cancer Biomedical Informatics Grid (caBIG) principles; and
- Develop and implement a system for utilizing central review for sites that do not have a local IRB.

As these tasks indicate, the Contractor's responsibilities are more complex than the standard management of two central IRBs. One unusual feature of this Initiative is that every decision the CIRBs make have an impact on the NCI's trial development and distribution system; consequently, all Standard Operating Procedures (SOPs) must be integrated with the relevant administrative procedures of the NCI's Protocol Information Office (PIO) in the Cancer Therapy Evaluation Program (CTEP), the Cancer Trials Support Unit (CTSU), and the Cooperative Groups' Operations offices. In addition, due to the high profile of this Initiative, sophisticated data management, analysis and presentation are required throughout all activities in the major tasks listed above. The Contractor must be prepared on a frequent and often unscheduled basis to provide data to NCI on the current status of any and all activities.

In addition to the above, all eligible small business concerns must document the ability of their staff (at all levels) to meet frequently/or on short notice (within the workday), face-to-face with CTEP Program Staff.

A copy of the draft Statement of Work (SOW) pertaining to this requirement, which is subject to revisions, may be accessed at Attachment 1 to this Sources Sought notice or it may be accessed on the NCI Office of Acquisitions External Website at URL: <http://rcb.nci.nih.gov/>. Once there, click on Current Request for Proposals. Under the Section entitled, "Sources Sought Announcement", click on the notice related to this requirement, i.e., click on **SS-ETSB-2007-48, entitled, "Central Institutional Review Board (CIRB) Initiative"**. Interested parties are expected to review this notice and the draft SOW to familiarize yourself with the requirements of this project; failure to do so will be at your firm's own risk.

Interested qualified small business organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in single-space and using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described above and in the draft SOW. All proprietary information should be marked as such. Statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address). Responses will be reviewed only by NIH personnel and will be held in a confidential manner.

All capability Statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to John R. Manouelian, Contracting Officer, at manouelj@mail.nih.gov in either MS Word, Wordperfect or Adobe Portable Document Format (PDF), by December 19, 2007, 3:30PM, EST. All responses must be received by the specified due date and time in order to be considered.